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In The

Supreme Court of the United States

TYCO HEALTHCARE GROUP LP, MALLINCKRODT, INC., LIEBEL-FLARSHEIM COMPANY, AND NEMOTO KYORINDO CO., LTD.,

Petitioners,

v.

MEDRAD, INC.,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit properly allowed reissue of a patent in accord with the plain language of the reissue statute, 35 U.S.C. § 251, well-settled precedent, and current Patent Office practice.

DISCLOSURE STATEMENT

Medrad, Inc. is wholly-owned by Schering Berlin Inc., which is wholly-owned by Bayer Gesellschaft fuer Beteiligungen mbH (Bayer G.f.B. mbH), which is wholly-owned by Bayer AG.

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35 U.S.C. § 251 ..... *passim*

Manual of Patent Examining Procedure § 1402 (8th ed. August 2001, revised August 2006) 3, 18

INTRODUCTION

The Petition presents no compelling reason supporting an exercise of this Court's jurisdiction. The Federal Circuit interpreted and applied the express limitations in the patent reissue statute, 35 U.S.C. § 251, consistent with existing precedent and in conformity with established Patent Office practice. A decision that comports with the express language of a statute, published precedent, and administrative practice does not warrant intervention by this Court.

In an effort to prove otherwise, Petitioners fashion a self-created parade of horribles allegedly flowing from the decision below. But they do so based on a series of mistaken premises that bear no resemblance to what was actually decided. For example, they contend that the decision below erroneously determined that Section 251 allows the correction of "any" defect identified in the patent, thereby departing from the statute's purported requirement that a reissue is warranted only when there has been a change in the actual language in the patent. Based on this purported mistake in construction, Petitioners argue that the decision allows reissue to be used to correct purely "procedural" errors, something Petitioners again identify as at odds with Section 251's terms. These two supposed errors then are said to be in glaring conflict with controlling Federal Circuit precedents such that they unravel the existing constraints on the reissue process to the detriment of the patent system.

Yet, when the realities of this case and the decision below are put in proper perspective, there is no parade and there are no horribles. To begin with, the decision below provides for the correction of an error falling within

Section 251's plain language – that is, an error made without deceptive intent that arose by reason of a patentee claiming more or less than it had a right to claim. This is not "any defect," as Petitioners would have it, but rather the specific type of error Congress expressly brought within reissue. Further, the Federal Circuit correctly concluded that Section 251 does not expressly require a change in the actual language of the patent's claims. No such limitation or distinction appears in the section. Nor does Section 251 provide for the exclusion of "procedural," as opposed to "non-procedural," errors. Finally, as the Federal Circuit's reasoning reveals, the decision below generated no conflict with any of its precedents. The denial of rehearing *en banc* regarding the court's narrow holding makes that plain as well.

Petitioners' hyperbolic assertions that the decision below will destabilize the patent process are misguided. Reissue in itself is rare, as less than 40,000 patents out of the over 7 million patents that have been issued have ever been reissued. Ever rarer still, this case involves a reissue patent that has itself been reissued. No other reported case has dealt with that fact pattern, and the Federal Circuit's decision on these particular facts is thus unlikely ever to be repeated.

Alternatively, there certainly is nothing destabilizing about a holding that adheres to the plain language of a statute and the case law construing it. Petitioners' counsel conceded at oral argument before the Federal Circuit that there is no precedent directly contrary to the result reached here. None is cited in the Petition either. *In re Serenkin*, 479 F.3d 1359 (Fed. Cir. 2007), a case decided by the Federal Circuit after this one, likewise underscores that the Federal Circuit's precedents preserve a consistent

distinction between those inadvertent errors that fall within Section 251's parameters and those advertent "errors" that do not. The Federal Circuit's decision below reinforces that distinction as well.

Finally, the Manual of Patent Examining Procedure ("MPEP"), the manual that the Patent Office and Patent Examiners follow in patent prosecution procedures, provides a non-exhaustive list of errors that may be corrected by reissue in Section 1402. (Res. App. at 1-7). Included in the list are errors such as the one here, that do not involve changes to the claim language. The decision in this case is thus also in conformity with established administrative practice.

When all is said and done, therefore, no destabilization follows from the decision below as far as the controlling statute, case law, or administrative practice is concerned. What would be a marked and destabilizing departure, however, is the adoption of the radical alterations to the statutory language proposed in the Petition. Under those alterations, reissue would be eliminated for a whole class of errors falling within the statute and properly deemed correctable by the Federal Circuit and the Patent Office under current practice.

None of the criteria warranting this Court's review are present and the Petition should be denied.[1]

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[1] Petitioners invite the views of the Solicitor General, a step that is unnecessary given the Federal Circuit's adherence to Section 251's plain language, the absence of any case conflict, the conformity with administrative practice, and the uniqueness of the fact pattern involved. Simply put, the Petition presents no issue of overriding public importance to patent practice or the patent process worthy of input from the Solicitor General.

COUNTERSTATEMENT OF THE CASE

I. BACKGROUND AND SUMMARY OF THE PROCEDURAL EVENTS

This case involves a dispute over the reissue of a patent. Reissue is an important, but rarely utilized, part of the patent system. It allows an inventor to correct certain types of errors in a patent application to protect the fruits of his or her labors. To that end, 35 U.S.C. § 251 provides for reissue:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent. . . .

The narrow issue implicated by the decision below is whether the unique circumstances underlying Medrad's request for reissue of U.S. Patent No. RE 37,602 ("the '602 patent"), as approved by the Patent and Trademark Office ("PTO"), meets these well-established and uncontroverted requirements. As outlined fully in the decision below, the undisputed facts reveal that these requirements are met and that reissue was warranted, just as Congress intended and the PTO concluded.

A. Medrad's Invention

The '602 patent pertains to vascular injection systems used with magnetic resonance imaging (MRI). MRI technology, introduced into clinical medical practice in the early 1980s, employs magnetic resonance (MR) scanners that utilize magnetic fields to produce high-resolution images of body tissue structure. MRI is particularly useful

for diagnosing and tracking diseases affecting the brain, central nervous system, neck, and large joints, and for detecting soft tissue disorders.

A contrast agent (a liquid pharmaceutical that enhances images) can be injected into a patient to enhance diagnostic images produced using MR scanners. An electro-mechanical device called an injector is sometimes used to inject a contrast agent into a patient. The magnetic attraction produced by MR scanners can, however, seriously disturb electronics and bring motors to a stop. At the same time, electronic components, such as might be used in an injector, produce "noise" that interferes with the MR scanner's ability to detect the faint signals that produce patient imaging.

To develop an injector for these MRI procedures, Medrad accordingly had to overcome the significant technical problems caused by the strong magnetic fields and highly sensitive signal-detection equipment. In 1996, it did so when it introduced the Spectris® injector – the first one ever offered for use in MRI procedures.

B. The History Of Medrad's Patents

The original U.S. Patent No. 5,494,036 ("the '036 patent") that covered Medrad's invention was filed on November 26, 1993, and issued on February 27, 1996. Less than two years later, Medrad requested reissue. This first reissue patent – U.S. Patent No. Re 36,648 ("the '648 reissue patent") – issued on April 11, 2000. During the examination of the '648 reissue patent, some of the claims in the original '036 patent were canceled, others narrowed based on newly considered prior art, and new claims were added that had not been in the original '036 patent.

In December 1999, while the '648 reissue patent was pending in the PTO, Petitioners' infringing Optistar MR injector system received FDA approval. Upon investigation, Medrad determined that Optistar infringed many of the claims that would be included in the '648 reissue patent when it issued. Consequently, after the '648 reissued, Medrad filed a complaint with the United States International Trade Commission ("ITC") pursuant to Section 337 of the Tariff Act of 1930. During the ITC action, Petitioners filed a Motion for Summary Determination (the ITC equivalent of a summary judgment motion) asserting the invalidity of the '648 reissue patent because of the inventors failure to file supplemental reissue declarations during examination of the patent.

Although the PTO did not request supplemental reissue declarations during the '648 reissue patent examination, Administrative Law Judge Luckern decided that (1) the patent statutes required Supplemental Declarations, (2) the PTO could not waive that requirement, and (3) the '648 reissue patent was invalid for purposes of the ITC's jurisdiction.

C. The '602 Patent

Given the adverse ruling, Medrad decided to request reissue from the PTO to correct the alleged error as determined by the ITC. Medrad provided all pertinent information it had to the PTO, including a comprehensive and detailed account of the ITC action and determination. (*See* Res. App. at 8-11). In the reissue application that resulted in the '602 patent, the inventors filed supplemental reissue declarations stating that they believed that the

prior '648 reissue patent was partly inoperative on two grounds.

First, the inventors explained that the patent was "partly inoperative for lack of a supplemental reissue declaration directed to the overclaiming error in [claims 9 and 13 of the '036 patent]." (Res. App. at 13). The inventors stated that they had believed that the "all errors" language in the original reissue declaration covered the overclaiming error, prior to the ITC ruling. (Res. App. at 13). They further stated that their omission of supplemental reissue declarations occurred "without any deceptive intention on [their] part." (Res. App. at 13).

Second, the inventors stated that they believed the '648 patent to be "partly inoperative for lack of a supplemental reissue declaration by all the inventors, in view of the initial determination" of invalidity by Judge Luckern. (Res. App. at 13-14). Thus, as part of the '602 reissue application, the inventors stated that they previously believed that their prior declarations were sufficient, and such error occurred "without any deceptive intention on [their] part." (Res. App. at 13).

Based on this two-part showing of inadvertent error, the second reissue patent – the '602 patent-in-suit – issued on March 26, 2002.

D. The Construction Of Section 251 In The District Court And On Appeal

In the underlying litigation, the parties filed summary judgment motions dealing with whether Medrad's '602 reissue patent fell within the scope of 35 U.S.C. § 251. The district court granted Petitioners' motion, dismissed

Medrad's claims, and held the '602 patent invalid on the ground that Section 251 purportedly "requires that some error in the specification, drawings, or claims of the patent be corrected as a result of the reissue process." *Medrad, Inc. v. Tyco Healthcare Group, LP*, 391 F. Supp.2d 374, 378 (W.D. Pa. 2005).

On appeal, the Federal Circuit reversed and held that a basis for reissue existed because the error that Medrad sought to correct arose "by reason of . . . the patentee claiming more or less than he had a right to claim in the patent" as required by Section 251. (Pet. App. A at 8a-10a). The Federal Circuit's decision rests on a thorough analysis of the discrete facts in this controversy, as applied to Section 251's express language. (Pet. App. A at 5a-7a). Specifically, the Federal Circuit found that:

> by including changes to the language of the claims that narrowed the scope of coverage and by correcting inventorship, the resulting '648 reissue patent claimed more than it had a right to claim in the patent without submitting a supplemental declaration to support the narrowing subject matter and the change in inventorship. The correction of such an error meets the express terms of Section 251, and thus serves as a basis for reissue.

(Pet. App. A at 10a).

Petitioners' Petition for Rehearing En Banc, raising the same unfounded construction and conflict issues presented to this Court, was denied.

REASONS FOR DENYING THE PETITION

II. THE FEDERAL CIRCUIT FOLLOWED SECTION 251'S EXPRESS LANGUAGE AND ESTABLISHED PRECEDENT IN UPHOLDING THE REISSUE OF THE '602 PATENT

A. The Federal Circuit's Decision Properly Interprets The Express Limitations Of The Reissue Statute In Accord With Controlling Principles Of Statutory Interpretation

The Federal Circuit's decision appropriately interprets the express limitations of 35 U.S.C. § 251, namely its provision that:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent. . . .

As the plain language of the statute provides, errors correctable under Section 251 must meet only three basic prerequisites:

(1) the error must have been made without deceptive intention;

(2) the error must result in the patent being deemed wholly or partly invalid or inoperative; and

(3) the invalidity or inoperability must occur "by reason of" a defective specification or drawing or the patentee claiming more or less than it had a right to claim in the patent.

The statute thereby encompasses errors in law, errors in drafting, errors of substance, procedural errors, attorney errors, inventor errors or any other type of inadvertent error that gives rise to the need for correction. *See, e.g., Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1574-75 (Fed. Cir. 1991) (reissue statute extends to errors of law and attorney errors that meet the statutory requirements). Any attempt to read the statute more narrowly is not faithful to its plain language or Congress's policy choice in defining the statute's remedial scope. *See In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986) ("in enacting the statute, Congress provided a statutory basis for correction of 'error.' The statute is remedial in nature, based on fundamental principles of equity and fairness, and should be construed liberally.").

Given the statute's actual requirements, there is nothing controversial about the Federal Circuit's reasoning upholding the PTO's allowance of the '602 reissue patent. The particular error corrected was held to meet the statute's express terms because it was inadvertent, rendered the '648 reissue patent invalid, and arose by reason of Medrad "claiming more than it had a right to claim in the ['648 reissue] patent." (Pet. App. A at 10a). None of these facts are disputed and Section 251's plain language directly supports the Federal Circuit's holding.

As a result, Petitioners' contention that the decision below renders "superfluous" the express limitations of Section 251 (Pet. at 9-10), does not withstand analysis. It is unclear how the Federal Circuit could render "superfluous" a phrase that it actually interpreted and then determined was met by the particular facts of this case. (Pet. App. A at 7a-8a, 10a). Petitioners nevertheless claim that the Federal Circuit's construction nullifies the Section's

requirement that the error correction must involve an actual change in the claims, specification, or drawings. (Pet. at 1-2, 10-11, 13). But that limiting language does not appear anywhere in the statute itself. Nor does Petitioners' companion "procedural" versus "non-procedural" distinction, the former purportedly falling outside Section 251, and the latter within it. All these supposed requirements are the product of Petitioners' editing, not Congressional directive.

Thus, it is Petitioners who are violating this Court's precedent by reading language and limitations into a statute that Congress did not provide for. If Congress had intended any of the limitations that Petitioners seek to include, it would have expressly included such limitations. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 454, 461-62 (2002). As this Court has stated "time and again":

> "[C]ourts must presume that a legislature says in a Statute what it means and means in a Statute what it says there. When the words of the Statute are unambiguous, then this first canon is also the last: 'judicial inquiry is complete.'"

Id. at 461-62 (citations omitted). By adhering to Section 251's plain language and rejecting Petitioners' efforts to read limitations into the section that Congress did not see fit to provide, the Federal Circuit reached a result in accord with this Court's precedent. (Pet. App. A at 6a-8a). A court's adherence to a statute's plain language provides no occasion for this Court's review.

B. The Federal Circuit's Interpretation Of The Limitation "By Reason Of The Patentee Claiming More Or Less Than He Had A Right To Claim" Creates Not Even An Arguable Conflict With Existing Federal Circuit Or CCPA Precedent

The Federal Circuit's construction of the phrase "by reason of the patentee claiming more or less than he had a right to claim" does not conflict with any prior holding of the Federal Circuit or the Court of Custom and Patent Appeals ("CCPA"). Rather, the Federal Circuit's construction is consistent with the decisions of that court, the CCPA and other federal courts of appeal, which have allowed patents to be reissued without a change in the actual claim language. The Federal Circuit's refusal to consider this case *en banc* further confirms that there is no conflict within Federal Circuit law on this point.

For example, in *Fontijn v. Okamoto*, 518 F.2d 610, 622 (C.C.P.A. 1975), the CCPA compared and distinguished the "by reason of the patentee claiming more or less" language in the first paragraph of Section 251 (the language at issue here), with the phrase "scope of the claims" in the last paragraph of Section 251.[2] *Id.* at 622-23. In its comparison and analysis, the CCPA confirmed that "claiming more or less" includes errors that do not involve actual changes to the words of the claims. *Id.* In contrast, the passage "enlarging the scope of the claims" (not at issue in the

[2] In *Fontijn*, the CCPA made this comparison to determine the meaning of the language in the last paragraph of Section 251 – "enlarging the scope of the claims" – which relates to the requirement that reissue must be applied for within two years of the issue date of the underlying patent if the actual claim language is broadened.

present case) was found to have a different meaning limited to the wording of the patent claims themselves. *Id.*

To the same effect, in *Brenner v. State of Israel*, 400 F.2d 789, 791 (D.C. Cir. 1968), the D.C. Circuit[3] held that the error of failing to file a certified copy of the foreign application upon which the inventor sought priority, an error that did not occur in the actual language of the claims, was correctable under Section 251 "by reason of the patentee claiming more or less than he had a right to claim." The court succinctly summarized how the failure to file the certified copy fit squarely within the statute:

> The plain meaning of this section would seem to cover this situation. The patent issued was partly inoperative (insofar as it did not include the priority right), and the patentee . . . did claim less than he had a right to claim.

Brenner, 400 F.2d at 791.

By parity of reasoning, in the Federal Circuit's *en banc* decision in *In re Bennett*, 766 F.2d 524 (Fed. Cir. 1985), a patentee's failure to file a correct reissue declaration in a timely manner was allowed to be corrected by the filing of a supplemental reissue declaration. *Id.* at 528. Although the corrected declaration was filed during the pendency of the reissue rather than in a new reissue application as was done in the present case, the *Bennett* decision underscores that "an error in compliance with Section 251" can be corrected in keeping with the remedial nature of the statute. *Id.* As the Federal Circuit noted,

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[3] The CCPA adopted and applied the holding of *Brenner* in *Fontijn*, 518 F.2d at 622-23, and the Federal Circuit expressly endorsed the holdings of *Brenner* and *Fontijn* in *Serenkin*, 479 F.3d at 1364.

"[t]he purpose of the reissue statute is to remedy errors." *Id.*[4]

Most recently, in *In re Serenkin*, a case decided after the decision below, the Federal Circuit expressly endorsed the holdings in *Brenner* and *Fontijn*, thereby confirming that a change in the claim's language, drawings or specifications is not a prerequisite to a valid reissue. On the contrary, the court pointed out that "the errors in those cases were the result of inadvertence, accident, or mistake, which clearly are appropriate bases for reissue." 479 F.3d at 1364.

By allowing the correction of an inadvertent error that indisputably resulted in a patentee claiming "more or less that it had a right to claim," the Federal Circuit's decision to uphold the reissue in this case faithfully adheres to the language of Section 251 and gives the statute its intended scope. It also aligns with existing precedent, like *Fontijn*, *Brenner*, *Bennett*, and *Serenkin*, construing the statute's plain terms as Congress intended.

In contrast, none of the cases cited by Petitioners hold that Section 251's "by reason of the patentee claiming more or less than he had a right to claim" is inapplicable to an inadvertent error that requires the filing of a second reissue patent with a supplemental reissue declaration. Indeed, the vast bulk of the cases cited either do not implicate the kind of inadvertent error at issue in this case

[4] The interpretation of Section 251 and the holding in this case is consistent with the interpretation of Section 251 and the holdings in *Fontijn, Brenner,* and *Bennett*. While the Federal Circuit distinguished the facts of those cases from the present case, their treatment of Section 251 is consistent with the Federal Circuit's holding below. (*See* Pet. App. A at 6a-6b).

or do not involve a construction of the language in Section 251 actually at issue. For those that do construe the relevant language, moreover, there is no even arguable conflict with the result reached.

For example, in *In re Serenkin*, the patent owner's attorney made the deliberate decision of choosing a later filing date during prosecution in exchange for including missing drawings. 479 F.3d at 1362-63. The patent owner subsequently filed a reissue application asking for an earlier filing date, claiming the attorney's deliberate choice was an error. In determining that reissue was not available to undo the deliberate decision to claim a later filing date, the Federal Circuit stated:

> Our case law holds that the deliberate action of an inventor or attorney during prosecution generally fails to qualify as a correctable error under § 251.

Id. at 1362.[5]

Similarly, in *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 882 F.2d 1556, 1566 (Fed. Cir. 1989), the applicant sought to add new claims via reissue, but again did not establish that the change in the claims was an "error without deceptive intent." *Id.* at 1565-66. The Federal Circuit acknowledged in dicta that precedent supports the notion that the "claiming more or less" language of Section

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[5] *In re Weiler* is similar. There the patent owner sought to pursue broadened claims on reissue, claims that the patent owner deliberately did not pursue (by filing a divisional application) during prosecution. 720 F.2d at 1582-83. The Federal Circuit thus held that the patent owner had not made an inadvertent error as Section 251 requires, but a deliberate choice. *Id.*

251 "*generally* refers to the scope of the claim." *Id.* at 1564 (emphasis added). The Federal Circuit did not hold, however, that the "claiming more or less language" *only* referred to the scope of the claim as Petitioners argue.

By comparison, in *In re Handel*, 312 F.2d 943 (C.C.P.A. 1963), the issue was whether claims that were actually amended during reissue were for the same "invention disclosed in the original patent" as required by Section 251, but the court did not analyze the portion of Section 251 at issue here.[6] 312 F.2d at 948. The CCPA reversed the Patent Office Board of Appeals decision to reject the reissue because the Board looked only to the claims rather than the entire disclosure of the patent to determine whether the new claims were directed at the same invention as in the original patent. *Id.* at 948-49.

And, in *In re Rogoff*, 261 F.2d 601 (C.C.P.A. 1958), the applicant's attempt to add new claims during reissue was rejected because the new claims were broader than the original claims and filed too late in violation of the last paragraph of Section 251, which prohibits broadening reissue applications that are filed more than two years after grant of an original patent. *Id.* at 604-06. The CCPA only addressed the portion of Section 251 at issue here in rejecting the applicant's alternative argument that the new claims being added were of the same scope as, and not

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[6] *In re Amos*, 953 F.2d 613 (Fed. Cir. 1991) is to the same effect. There, the applicant also sought to add new claims via reissue, but the reissue was rejected because the applicant had not demonstrated it had an "intent to claim" the subject matter of the new claims in the original patent disclosure. *Id.* at 619. The Federal Circuit only set forth the "claiming more or less" language in Section 251 in the general way quoted by Petitioners but did not analyze or apply the language because it was not at issue in that case. *Id.* at 616.

broader than, the original claims. *Id.* at 605-06. The CCPA noted that the new claims were not of the same scope and even if they were, the statute provides no basis to merely add new claims of the same scope as the original claims.[7] 261 F.2d at 605-06.

Finally, and to like effect, in *In re Dien*, 680 F.2d 151 (C.C.P.A. 1982), the applicant never alleged there was a defect in the patent or that the patent was invalid in whole or in part, but merely sought reissue of a patent having the same claims, specification and drawings over some prior art that was not submitted to the Patent Office. *Id.* at 152. "In other words, no defect in the patent is alleged nor is any change in the patent sought." *Id.*

Here, in contrast, Medrad alleged and corrected an inadvertent error in the '648 reissue patent, failing to file a supplemental declaration, acknowledged by both the ITC and the Federal Circuit. The '602 reissue patent thus was not in identical form to the '648 patent, as the CCPA in *In re Dien* would define it, because that request for reissue specifically corrected the error of the lack of a

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[7] In *Slip Track Sys., Inc. v. Metal Lite, Inc.*, 159 F.3d 1337 (Fed. Cir. 1998), there was no reissue patent at all. Rather, the Federal Circuit indicated that a reissue patent was not an option available to a patent owner who sought to litigate priority between two patents. *Id.* at 1341. Reissue was not available because the patent owner did not allege there was an error in the patent, but rather, alleged that the Patent Office erred in issuing another patent for the same invention. *Id.* The Federal Circuit thus cited a previous holding that a reissue application may not be filed "solely on the ground that the PTO erred in issuing two patents for the same invention." *Id.* The passage cited by Petitioners is a cursory general description of the statute that was not further analyzed or applied.

supplemental declaration.[8] And, unlike in *In re Dien* and Petitioners' other cited cases, the error corrected in this case satisfies Section 251's actual terms.

In sum, far from creating a conflict with the decision below, Petitioners' string of cases simply highlights that the Federal Circuit comprehends when Section 251 applies and when it does not. That guidance is sufficient for the bench, bar, and PTO alike and creates no reason for this Court to intervene. This is particularly true given the uniqueness of this case and the rarity of reissue. None of the cases cited by Petitioners involve the same facts that are present in this case, and only 40,000 of the 7 million patents issued by the PTO have ever been reissued. Moreover, established PTO practice, as evidenced by the Section 1402 of the MPEP (Res. App. at 1-7), allows for the correction of errors in reissue such as the one here, that do not involve changes to the claim or specification language or the drawings. For example, the MPEP indicates that one of the "most common bases for filing a reissue application" is that the applicant "failed to or incorrectly claimed foreign priority" and approvingly cites *Brenner* and *Fontijn* as examples. (Res. App. at 2, 3-4). The infrequency of reissue, coupled with the lack of a conflict in the case law, and established administrative practice dictates that this

[8] Likewise, in *In re Clement*, 131 F.3d 1464 (Fed. Cir. 1997), reissue was rejected because the new claims sought to be added would improperly recapture subject matter that had been surrendered during prosecution. *Id.* at 1472. Since no error was alleged in, and no change was made to, the original claims (1-18), they could not support reissue either. *Id.* It was these original claims, lacking error or changes, that the Federal Circuit was referring to when it cited the "identical form" statement from *In re Dien*. *Id.*

case does not present a significant or reoccurring issue warranting this Court's attention.

CONCLUSION

The decision below addresses a unique set of facts utilizing a rare procedure, follows the express language of Section 251, and is in accord with controlling precedent and PTO practice. This Court should deny the petition for writ of certiorari.

Respectfully submitted,

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Manual of

PATENT

EXAMINING

PROCEDURE

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[SEAL]

U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

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1402 Grounds for Filing [R-5]

A reissue application is filed to correct an error in the patent which was made without any deceptive intention, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid. An error in the patent arises out of an error in conduct which was made in the preparation and/or prosecution of the application which became the patent.

There must be at least one error in the patent to provide grounds for reissue of the patent. If there is no error in the patent, the patent will not be reissued. The present section provides a discussion of what may be considered an error in the patent upon which to base a reissue application.

In accordance with 35 U.S.C. 251, the error upon which a reissue is based must be one which causes the patent to be "deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent." Thus, an error under

35 U.S.C. 251 *has not been presented* where the correction to the patent is one of spelling, or grammar, or a typographical, editorial or clerical error which does not cause the patent to be deemed wholly or partly inoperative or invalid for the reasons specified in 35 U.S.C. 251. These corrections to a patent do not provide a basis for reissue (although these corrections may also be included in a reissue application, where a 35 U.S.C. 251 error is already present).

These corrections may be made via a certificate of correction; see MPEP § 1481.

The most common bases for filing a reissue application are:

(A) the claims are too narrow or too broad;

(B) the disclosure contains inaccuracies;

(C) applicant failed to or incorrectly claimed foreign priority; and

(D) applicant failed to make reference to or incorrectly made reference to prior copending applications.

An attorney's failure to appreciate the full scope of the invention was held to be an error correctable through reissue in the decision of *In re Wilder,* 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984). The correction of misjoinder of inventors in divisional reissues has been held to be a ground for reissue. See *Ex parte Scudder,* 169 USPQ 814 (Bd. App. 1971). The Board of Appeals held in *Ex parte Scudder,* 169 USPQ at 815, that 35 U.S.C. 251 authorizes reissue application to correct misjoinder of inventors where 35 U.S.C. 256 is inadequate.

Reissue may no longer be necessary under the facts in *Ex parte Scudder, supra,* in view of 35 U.S.C. 116 which provides, *inter alia,* that:

> "Inventors may apply for a patent jointly even though . . . (3) each did not make a contribution to the subject matter of every claim in the patent"

See also 37 CFR 1.45(b)(3).

If the only change being made in the patent is correction of the inventorship, this can be accomplished by filing a request for a certificate of correction under the provisions of 35 U.S.C. 256 and 37 CFR 1.324. See MPEP § 1412.04 and § 1481. A Certificate of Correction will be issued if all parties are in agreement and the inventorship issue is not contested.

A reissue was granted in *Brenner v. State of Israel,* 400 F.2d 789, 158 USPQ 584 (D.C. Cir. 1968), where [1402] the only ground urged was failure to file a certified copy of the original foreign application to obtain the right of foreign priority under 35 U.S.C. 119(a)-(d) before the patent was granted.

In *Brenner,* the claim for priority had been made in the prosecution of the original patent, and it was only necessary to submit a certified copy of the priority document in the reissue application to perfect priority. Reissue is also available to convert the "error" in failing to take any steps to obtain the right of foreign priority under 35 U.S.C. 119(a)-(d) before the patent was granted. >See *Fontijn v. Okamoto,* 518 F.2d 610, 622, 186 USPQ 97, 106 (CCPA 1975) ("a patent may be reissued for the purpose of establishing a claim to priority which was not asserted, or which was not perfected during the prosecution of the

original application")< In a situation where it is necessary to submit for the first time both the claim for priority and the certified copy of the priority document in the reissue application, and the patent to be reissued resulted from a utility or plant application which became the patent to be reissued was filed on or after November 29, 2000, the reissue applicant must (where it is necessary to submit for the first time the claim for priority) also file a petition for an unintentionally delayed priority claim under 37 CFR 1.55(c) in addition to filing a reissue application. See MPEP § 201.14(a).

The courts have not addressed the question of correction of the failure to adequately claim benefit under 35 U.S.C. 119(e) in the application (which became the patent to be reissued) via reissue. If the application which became the patent to be reissued was filed prior to November 29, 2000, correction as to benefit under 35 U.S.C. 119(e) would be permitted in a manner somewhat analogous to that of the priority correction discussed above. **>Where< the application, which became the patent to be reissued, was filed on or after November 29, 2000>, reissue may be employed to correct an applicant's mistake by adding or correcting a benefit claim under 35 U.S.C. 119(e). A petition under 37 CFR 1.78(a)(6) for an unintentionally delayed claim under 35 U.S.C. 119(e) would *not* be required in addition to filing a reissue application.<.

Section 4503 of the American Inventors Protection Act of 1999 (AIPA) amended 35 U.S.C. 119(e)(1) to state that:

> No application shall be entitled to the benefit of an earlier filed provisional application under this subsection unless an amendment containing the specific reference to the earlier filed provisional application is submitted at such

> time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this subsection. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section ***during the pendency of the application.*** (Emphasis added.)

**>The court in *Fontijn* held that 35 U.S.C. 251 was sufficiently broad to correct a patent where the applicant failed to assert or failed to perfect a claim for foreign priority during the prosecution of the original application even though 35 U.S.C. 119(b) at that time required a claim and a certified copy of the foreign application to be filed *before the patent is granted.* Similarly, the Office may grant a reissue for adding or correcting a benefit claim under 35 U.S.C.119(e) that requires the benefit claim to a provisional application be submitted *during the pendency of the application.*<.

Correction of failure to adequately claim benefit under 35 U.S.C. 120 in an earlier filed copending U.S. patent application was held a proper ground for reissue. *Sampson v. Comm'r Pat.,* 195 USPQ 136, 137 (D.D.C. 1976). If the utility or plant application which became the patent to be reissued was filed on or after November 29, 2000, the reissue applicant must file a petition for an unintentionally delayed priority claim under 37 CFR 1.78(a)(3) in addition to filing a reissue application. See MPEP § 201.11. For treatment of an error involving disclaimer of a benefit claim under 35 U.S.C. 120, see MPEP 1405. If the utility or plant application which became the patent to be reissued was filed prior to November 29, 2000 and

therefore, not subject to the eighteen-month publication (e.g., one of the categories set forth in 37 CFR 1.78(a)(2)(ii)(A)-(C)), a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) would *not* be required to add/correct the benefit claim in the reissue application. This is so, even if the reissue application was filed on or after November 29, 2000. On the other hand, if applicant fails to file an amendment to add a claim for benefit of a prior-filed reissue application in a later-filed reissue application within the time period set forth in 37 CFR 1.78(a)(2), then a petition for an unintentionally delayed benefit [1403] claim under 37 CFR 1.78(a)(3) along with the surcharge set forth in 37 CFR 1.17(t) would be required if the later-filed reissue application is a utility or plant application filed on or after November 29, 2000 irrespective of whether the original application which became the original patent was filed prior to November 29, 2000. This is because the benefit claim is between the later-filed reissue application and the prior-filed reissue application and the benefit claim is not being added to make a correction as to a benefit of the original patent.

A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) following a restriction requirement is not considered to be error causing a patent granted on elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Thus, such applicant's error is not correctable by reissue of the original patent under 35 U.S.C. 251. See MPEP § 1412.01.

A reissue may be based on a drawing correction that is substantive in nature, because such a correction qualifies as correcting an "error" under 35 U.S.C. 251 that may properly be deemed to render the patent wholly or partly

inoperative. A reissue application cannot be based on a non-substantive drawing change, such as a reference numeral correction or addition, the addition of shading, or even the addition of an additional figure merely to "clarify" the disclosure. Non-substantive drawing changes may, however, be included in a reissue application that corrects at least one substantive "error" under 35 U.S.C. 251.

* * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Reissue Patent

Application of U.S. Patent No. Re. 36,648:

Uber, III et al.	: Group Art Unit: 3737
Appln. No.: 09/714,907	: Examiner: B. Casler
Filed: November 16, 2000	:

Title: PATIENT INFUSION SYSTEM FOR USE WITH MRI

* * * * *

June 8, 2001

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner
of Patents and Trademarks
Washington, D.C. 20231

Sir:

This IDS contains two parts. For the first part, the Applicant submits seven (7) sheets (forms PTO-1449) listing a number of references that the Applicant asks the Examiner to consider. For the second part, the Applicant details specific facts (prior to and after the filing of the patent application on which this application is based) concerning certain activities by the assignee of this application, Medrad, Inc., that the Applicant would like the Examiner to consider pursuant to the provisions of the "on-sale" bar codified at 35 U.S.C. § 102(b).

II. Factual Information for the Examiner's Consideration Under the "On-Sale" Bar Codified by 35 U.S.C. § 102(b)

A. Summary of the History of This Application and Related Applications

1. The application that matured into U.S. Patent No. 5,494,036 (Exhibit 1) ("the '036 patent") was filed on November 26, 1993, and bore Serial Number 08/158,055 ("the '055 application"). The '036 patent issued on February 27, 1996. (Exhibit 1.)

2. By the assignment recorded at the U.S. Patent and Trademark Office on February 14, 1994, at Reel 6897, Frame 0942, Medrad, Inc. is the assignee of the '036 patent.

3. On February 23, 1998, within two years of the issue date of the '036 patent, the Applicant filed an application to reissue the '036 patent. (Exhibit 2.) That application bore Serial Number 09/027,852 ("the '852 application") and ultimately matured into U.S. Patent No. Re. 36,648 (Exhibit 2) ("the '648 patent").

4. By reissue, the Applicant sought to broaden the scope of protection for the invention because the Applicant believed that the '036 patent was inoperative for claiming less than the Applicant originally had the right to claim. (*See* the Reissue Declaration filed in the '852 application, attached as Exhibit 3.) The '852 application issued as the '648 patent on April 11, 2000. (Exhibit 2.)

5. To more fully claim the invention described in the '852 application, the Applicant filed a continuation on April 7, 2000, just prior to the issuance of the '648 patent. The continuation reissue application bears serial number 09/545,582 ("the '582 application") and is currently pending.

6. After issue of the '648 patent (Exhibit 2), Assignee, Medrad, Inc., initiated an investigation by the International Trade Commission ("ITC") against several defendants, alleging, *inter alia*:, infringement of certain claims of the '648 patent by the named defendants.

7. The ITC commenced the investigation, entitled *In the Matter of: Certain Magnetic Resonance Injection Systems, Components Thereof, and Molds Therefor* (Investigation No. 337-TA-434).

8. On September 26, 2000, Administrative Judge Paul J. Luckern issued Order No. 16 in which he determined that the '648 patent was invalid under 37 C.F.R. § 1.175(b)(1) for lack of a supplemental reissue declaration directed to the overclaiming and inventorship errors corrected thereby.

9. Since the '648 patent was found to be invalid, the ITC terminated its investigation.

10. To correct the "error" in the '648 patent" identified by Judge Lucken in his September, 2000 decision, the Applicant filed an application to reissue the '648 patent. (Exhibit 4, which is a copy of the Reissue Declaration therefor.)

11. The reissue application of the '648 patent was filed on November 16, 2000 and bears Serial Number 09/714,907 ("the '907 application"). The '907 application is the instant application.

12. In view of this history, the Applicant points out that there are now two applications currently pending that relate to the underlying '036 patent, the continuation of the original reissue application (which is the '582 application) and the reissue of the '648 reissue patent (which is the '907 application) introduced publicly. Accordingly, the mere development of the basic concept

requirements of the MR injector in April and July of 1992, with the absence of design particulars, indicates that the invention was not ready for patenting at that time.

III. Conclusion

104. The facts and the law both support the conclusion that the activities of Medrad, Inc. more than one year before the filing of the '055 application fail to render the claims of this application unpatentable under 35 U.S.C. § 102(b). In the aggregate, the facts simply do not rise to a sufficient level to trigger application of the "on-sale" bar under 35 U.S.C. § 102(b).

Consideration of the foregoing and enclosures plus the return of a copy of the enclosed forms PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited.

Respectfully submitted,
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IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

In re Reissue Application of:	)	
UBER et al.	)	
	)	Art Unit: 3737
U.S. Reissue Patent No.: 36,648	)	
Issued: April 11, 2000	)	
	)	Examiner:
Filed: February 23, 1998	)	Brian L. Casler
For: PATIENT INFUSION SYSTEM FOR USE WITH MRI	)	

REISSUE DECLARATION

Assistant Commissioner
for Patents
Box Reissue
Washington, D.C. 20231

Dear Sir:.

We, Arthur B. Uber, III, Seid Waddell, John Stulen, Jon E. Manley, Salvatore J. Dedola and Gordon C. Newell hereby declare that: our residences, post office addresses and citizenship are as stated below next to our names; we believe that we are the original, first and sole inventors of the subject matter described and claimed in U.S. Patent No. RE 36,648, granted on April 11, 2000, and for which a reissue patent is sought on the invention entitled "Patient Infusion System For Use With MRI," the specification of which is attached hereto; we have reviewed and understand the contents of the above-identified reissue application, including the claims therein; we acknowledge the duty to disclose information which is material to patentability as defined in Title 37. Code of Federal Regulations, Section 1.56; for the reasons provided below, we each

verily believe the original reissue patent to be partly inoperative; and all errors specified herein and corrected in this reissue application arose without any deceptive intention on our part.

Administrative Law Judge Paul J. Luckern of the U.S. International Trade Commission ("ITC") issued Order No. 16, in ITC Investigation No. 337-TA-434, on September 26, 2000 (hereinafter "Order No. 16") (a copy of which is submitted herewith). Specifically, Order No. 16 is an initial determination that the original reissue patent is invalid under 37 C.F.R. § 1.175(b)(1) for lack of a supplemental reissue declaration directed to the overclaiming and inventorship errors that were corrected in U.S. Patent No. RE 36,648.

We believe U.S. Patent No. RE 36,648 to be partly inoperative for lack of a supplemental reissue declaration directed to overclaiming in the original patent, U.S. Patent No. 5,494,036, which rendered that patent partly inoperative by reason of our claiming more than we had a right to claim in the patent. Specifically, we had claimed more than we had a right to claim in paragraph (d) of each of claims 9 and 13, by failing to recite the "communicating link" as a "communicating control link". Although we believed and intended that the language "all errors" in our reissue declaration included the overclaiming as well as the specifically recited underclaiming, Administrative Law Judge Paul J. Luckern disagreed, in Order No. 16, and found U.S. Patent No. RE 36,648 invalid because we failed to specifically recite this overclaiming error in the reissue declaration.

We also believe U.S. Patent No. RE 36,648 to be partly inoperative for lack of a supplemental reissue declaration

by all the inventors, in view of the initial determination by Administrative Law Judge Paul J. Luckern in Order No. 16. We, the named inventors, are each declarants herein and we each declare that we have no disagreement with the inventorship change in U.S. Patent No. RE 36,648. This declaration supplements the reissue declarations made in the application that resulted in U.S. Patent No. RE 36,648, which reissue declarations were previously believed to have been sufficient under the revised reissue rules.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Reissue Declaration is directed.

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We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this Reissue Declaration is directed.

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